UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

RENÉE MARIE BUMB
CHIEF UNITED STATES DISTRICT JUDGE

MITCHELL H. COHEN COURTHOUSE
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LETTER ORDER

October 3, 2024

***Via* ECF**
Counsel of record

Re: ***In re Valsartan, Losartan, and Irbesartan Products Liability Litigation*, MDL No. 2875**

Dear Counsel:

Due to an unavoidable scheduling conflict, the Court hereby adjourns the previously scheduled oral argument on Tuesday, October 8, 2024. The oral argument will now take place on Thursday, October 10, 2024, at 2:30 p.m. in Courtroom 1 of the United States Post Office and Courthouse, located on the 3rd floor, 401 Market Street, Camden, New Jersey 08101.

The Court has exhaustively reviewed the parties' submissions addressing certain questions raised by the Court during the hearings held earlier in September 2024 [ECF Nos. 2844, 2855, 2869], as well as the parties' recent letters regarding causation [ECF Nos. 2877, 2879]. Despite this exhaustive review, the Court continues to have unresolved concerns about the matter that will be addressed during oral argument.

Additionally, in order to assist the parties as well as the Court in preparing for trial, the Court sets forth the following framework.

First, the determination of "adulteration" – namely whether the Defendants' VCDs were adulterated and, if so, for what time period – is solely for the jury to make. To be clear, no testimony will be permitted suggesting

that the mere fact of the FDA's finding of adulteration and recall in November 2018 is sufficient to establish adulteration retroactively to 2012. In this regard, Dr. Rena Conti's testimony will not be permitted to the extent she opines as such. Plaintiffs continue to rely upon *Blue Cross Blue Shield Ass'n v. GlaxoSmithKline LLC*, 2019 WL 4751883, at *1 (E.D. Pa. Sept. 30, 2019) for this proposition. As Defendants point out, however, this case is inapposite. There, the relevant time period for which the third-party payors sought damages was after the FDA's finding of adulteration. *See Blue Cross Blue Shield Ass'n v. GlaxoSmithKline LLC*, 417 F. Supp. 3d 531, 541, 546 (E.D. Pa. 2019).

Second, it appears that Plaintiffs' position is that a finding of non-conformity with cGMPs is sufficient to establish adulteration and that Plaintiffs will rest upon the FDA Warning Letter's determination of cGMP violations to establish this at trial. Yet, even after considering the FDA Warning Letter, Judge Kugler ruled on summary judgment that genuine disputes of material facts existed as to Defendants' conformity with cGMPs [ECF No. 2692]. The parties shall be prepared to discuss this tension and whether a finding of non-conformity with cGMPs alone may establish adulteration.

Finally, if adulteration is found by the jury for some time period, the issue of damages will be addressed using the "benefit of the bargain" approach. This, too, is an issue for the jury to decide. Yet Plaintiffs at times seem to conflate arguments with admissible evidence. It appears that Plaintiffs' theory is that they are entitled to a full refund because the VCDs were economically worthless as there can be no legal market for adulterated drugs. But this alone is an argument, not evidence. Plaintiffs seek to present a counter-factual world in which VCDs were never sold in the first place and thus could have no economic value; but this is not reality. If this argument is made, it seems that Defendants should be permitted to enter the counter-factual world as well and introduce their alternative drug argument and evidence of other drugs that the TPPs may have covered in the absence of VCDs to mitigate the damages that may be owed.

Plaintiffs also appear to argue that they are entitled to a full refund because the VCDs were so fundamentally flawed as to render them worthless and of no therapeutic value due to their alleged adulteration. If so, it seems

that Defendants should be allowed to counter with evidence of continuing therapeutic value and minimal risk to patients. This is of concern to the Court, however, as it implicates questions of causation. The parties' recent submissions on causation likewise give the Court pause. The issue of causation, namely nitrosamine's carcinogenic risk, appears to be integral even in this TPP economic loss case. In other words, it is the "elephant in the room." Failure to address it would likely confuse the jury and the issues, leading to an unwieldy and possibly unfair trial.

The parties shall be fully prepared to address all issues raised herein at oral argument.

Sincerely,

s/Renée Marie Bumb
RENÉE MARIE BUMB
Chief United States District Judge